

Remarks

This application has been carefully reviewed in light of the final Office Action dated January 22, 2008. Claims 15 to 52 remain in the application, of which claims 15, 46 and 47 are the independent claims. Reconsideration and further examination are respectfully requested.

Initially, Applicants thank the Examiner for the courtesies extended to Applicants' representatives in the telephonic interview conducted on May 1, 2008, in which the outstanding claim rejections were discussed. As discussed in the interview, the Office Action's contention that "Applicants have not demonstrated any significant patentable distinction between the Ueda delivery capsule and the instant delivery capsule" constitutes premature and inappropriate burden shifting. In this regard, the Office Action has failed to make a *prima facie* case of obviousness, as all of the claim limitations are neither taught nor suggested by the prior art, as admitted in the Office Action and as set forth in greater detail below. Accordingly, the Office Action's requirement that Applicants demonstrate a "significant patentable distinction" between the cited reference and the claimed invention constitutes an inappropriate and premature attempt to shift onto Applicants the burden of rebutting an obviousness showing that has yet to be made by the Office. *See, e.g.*, MPEP § 2145 ("If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case." (emphasis added)). While one approach to rebutting an obviousness rejection may include "evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art," (which the Examiner indicated in the telephonic reference was intended by the Office Action's language requiring the demonstration of a "significant patentable distinction" and asserting that the "capsule of Ueda is functionally equivalent to the capsule of the instant invention"), the MPEP indicates numerous different forms that rebuttal evidence may take (*see, e.g.*, MPEP § 2145), none of which are mandatory. Even were the Office Action to succeed in establishing a *prima facie* case of obviousness of the claimed invention (which Applicants vigorously assert has not yet occurred), it would be inappropriate for the Office to

require one particular form of rebuttal evidence in lieu of another, as “[o]ffice personnel should consider all rebuttal arguments and evidence presented by applicants.” MPEP § 2145. While no agreement was reached in the Interview, Applicants thank the Examiner for the indication that in view of the Interview and the foregoing arguments, “she will reconsider her position on the record and possibly withdraw the final office action” (Examiner’s Interview Summary of May 6, 2008, Continuation Sheet).

Claims 51 and 52 were rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. In this regard, the Office Action asserts that “[c]laims 51 and 52 appear to require 4 layers whereas claim 15 only provides a recitation of two layers.” In response, Applicants respectfully submit that claims 51 and 52 reference only the two layers of material for which there is adequate antecedent basis in claim 15. The Office Action’s assertion that “[c]laim 15 from which these claims depend, recite [*sic*] a dividing wall and a septum, each having two layers” is erroneous. Claim 15 recites, in part, “the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material” (emphasis added). None of claims 15, 51 or 52 “require 4 layers,” as asserted in the Office Action. Accordingly, reconsideration and withdrawal of these 35 U.S.C. § 112, second paragraph rejections are respectfully requested.

Claims 15 to 50 were rejected under 35 U.S.C. § 103(a) over European Patent Application No. EPO 0 211 079 (“Ueda”) in view of International Patent Application Publication No. WO 97/35537 (“Brown”). Reconsideration and withdrawal of these rejections are respectfully requested.

Independent claim 15 is directed to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

Independent claim 46 is directed to a method of encapsulation comprising supplying two films of material capable of deforming plastically on heating and/or when partially solvated,

heating the films and/or applying solvent; forming the films into suitably shaped capsule portions, supplying respective substances to be encapsulated to capsule portions of each film, supplying a respective film of a dividing septum material to each of the filled capsule portions, and sealing the capsule portions and septum material together to form a capsule having at least two separate chambers.

Independent claim 47 is directed to encapsulation apparatus comprising means for supplying two films of material to an encapsulation unit, means for plastically deforming each film to form suitably shaped capsule portions, means for supplying respective substances to be encapsulated to the respective capsule portions of each film, means for supplying a respective film of dividing septum material to each of the filled capsule portions, and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers.

The applied references are not seen to disclose or suggest the features of the claimed invention, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material (as in claim 15) and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions (as in claims 46 and 47).

As has been repeatedly stressed by the Applicants, “[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03; *see also In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In this respect, the Office Action concedes that Ueda and Brown are entirely silent as to the particular claim feature of a dividing wall or a septum having two layers of material. Accordingly, as this claim feature is nowhere taught in or suggested in the cited references, the outstanding 35 U.S.C. § 103(a) rejection of claims 15 to 50 fails to meet the standard for *prima facie* obviousness. Nevertheless, the Office Action again contends that “Applicants have not demonstrated any significant patentable distinction between the Ueda delivery capsule and the instant delivery capsule.” Office Action, pp. 4-5. The requirement that the patentable distinction be

“significant” is nowhere to be found in the MPEP, the Code or the Rules. It appears that the Office Action is suggesting one possible manner for rebutting a showing of obviousness. As discussed in the interview, however, the Office Action has failed to make a *prima facie* case of obviousness, so there is no burden upon Applicants to make any such rebuttal. Rather, Applicants respectfully request that the outstanding 35 U.S.C. § 103(a) rejection of claims 15 to 50 be withdrawn as improper.

As discussed in Applicants’ previous responses and in the interview, the claimed invention is believed to be patentably distinct over the combination of Ueda and Brown, as nowhere is either of these references seen to disclose (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material or (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions. Ueda is seen to be directed to a multi-chamber capsule divided by *a single film* into a plurality of chambers. *See, e.g.*, Ueda p. 4, ll. 8-20; p. 9, ll. 7-25. More particularly, Ueda teaches a system and method in which films are deformed into cavities in a rotating drum, such that the cavities are filled when the opening to these cavities are in a vertical or substantially vertical position. *See* Ueda, Figure 2; p. 9, ll. 7-25. Alternatively, Ueda discloses filling one cavity when the cavity is in a horizontal position, applying a septum material to the top of this cavity, applying the second filling material to the top of the septum and then applying the second capsule cavity material on top of both the septum and the second filling material. *See* Ueda, p. 10, l. 17 – p. 11, l. 5.

Ueda’s multi-chamber capsule, being divided by a *single film*, suffers from a number of deficiencies when compared to a delivery capsule of the claimed invention. For example, a delivery capsule of the claimed invention comprises two capsule cavities that can be *separately filled and sealed* prior to being adhered together, a far more simple and efficient filling process than that of Ueda. Moreover, the two capsule cavities of the claimed delivery capsule can be *partially filled* (in contrast to Ueda and Brown, which both rely on the filling process to deform the film and create the cavities) prior to sealing and adhesion together. The *partially filled* delivery capsule enjoys a greater propensity for distortion of shape (*e.g.*, greater “softness”) such

that, for example, the capsules may be more easily swallowed. Further, given the importance of the accuracy in delivery capsules, the ability to only partially fill the cavities of the claimed delivery capsules allows for *metered doses*. All of these benefits redound from the claimed invention's utilization of a dividing wall or a septum having two layers of material; accordingly, none of these benefits are available to a capsule divided by a *single film*, as taught in Ueda.

Brown is not seen to remedy the foregoing deficiency of Ueda. Brown is seen to be generally directed to a method of encapsulation for forming capsules. See Brown, Abstract. The capsules are formed by bringing together two opposed capsule halves in the shape of open hemispheres, such that they form a single undivided chamber. See, e.g., Brown, pp. 5-6 (wherein hemispherical indentations on opposing drum receive gelatin ribbons which deform to line said indentations and are brought together to form capsules). Nowhere is Brown seen to disclose or suggest a septum or a dividing wall of any kind, let alone a dividing wall or septum having two layers of material adhered together with an adhesive material.

Accordingly, the applied references, whether taken alone or in combination, are not seen to disclose or suggest the features of independent claims 15, 46 and 47, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material, and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions.

The other claims currently under consideration in the application are dependent from the independent claims discussed above and therefore are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

In view of the foregoing remarks, all of the claims under consideration are believed to be in condition for allowance and such action is respectfully requested at the Examiner's earliest convenience.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Applicants' undersigned attorney may be reached in our Orange County office by telephone at 949.851.0633. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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